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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,463	02/08/2007	Ippeita Dan	060380	7029
23850 7590 07/07/2009 KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. Suite 400 WASHINGTON, DC 20005			EXAMINER BRUTUS, JOEL F	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,463	Applicant(s) DAN ET AL.	
	Examiner JOEL F. BRUTUS	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/15/2006, 5/15/2006 and 5/14/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 11, 13, 16 are objected to because of the following informalities: In claim 13, line 1, "tran scanial" needs to be changed to --transcranial--. In claim 16 lines 3, "a distances" should be changed to --a distance--. Regarding claim 11, in line 7 after ";" the word "and" should follow. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 11 recites the limitation "in accordance with the method according to claim 1" in lines 10-11. There is insufficient antecedent basis for this limitation in the claim. Because claim 11 refers to a brain function measuring apparatus whereas claim 1 is a method claim. An apparatus claim can not depend on a method claim. Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 10 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is directed to a software program for realizing a method, but the software programs need to be used in conjunction with a computer or processor capable of running the program. The software program alone is not patentable.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-16 are- rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita et al (US Pat: 6,611,698) in view of Lagerlund et al (Determination of 10-20 system electrode locations using magnetic resonance image scanning with markers) and/or Towle et al (The spatial location EEG electrodes: locating the best fitting sphere relative to cortical anatomy).

Regarding claims 1 and 11, Yamashita et al teach a highly reliable optical measuring instrument for multi channel simultaneous measurement has an intensity of light emitted from a light source modulated at different frequencies and the light is

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applied to multiple positions of a test object. The light which is detected from the test object is converted into electric signals by a photodiode, and modulation signals are detected by a lock-in amplifier module. The signals are processed as information on the test object interior by a processing unit. Light is applied sequentially from a light source in a preparatory measurement step prior to final measuring, and the signal level of the detection light is measured for each light applied position [see abstract].

Yamashita et al teach in figs 3-5, a plurality of light incident positions, detection position and measurement position (these positions are used as irradiation point and detection point on a surface of the subject, emphasis added). The space between the adjacent light applied position and detection position is not restricted to 3 cm. It can be changed according to the site of measurement [see column 7 lines 27-29].

Yamashita et al teach in FIG. 1 an optical measuring instrument wherein light is applied to the test object, for example, the skin of the head, and light is reflected inside the test object thereby to detect the light passing through said test object and to image the cerebral interior, the number of measurement channels, namely the number of measurement positions are assumed as 12, and the number of signals to be measured (analog/digital conversion channels) are assumed as 24. The light source comprises four light modules. Each light module comprises two semiconductor lasers each emitting the light of multiple wavelengths from visible to infrared ray ranges, for example, 2 wavelengths of 780 nm and 830 nm. Values of these two wavelengths are not restricted to 780 nm and 830 nm. Further, the number of wavelengths is not limited

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to two. A light emitting diode may be used as this light source instead of a semiconductor laser [see column 5 lines 60-67 and column 6 lines 1-35].

These measurements are controlled by a control unit. Using the amount of detection light of two wavelengths for each measurement position, these recorded signals are processed at the processor to calculate the changes in oxygenated hemoglobin concentration accompanying the cerebral activities, changes in deoxygenated hemoglobin concentration and changes in the entire hemoglobin concentration as a total of these hemoglobin concentrations. The result of calculation is converted in an image and is shown as a topographic image on the display unit [see column 9 lines 1-19 and column 8 lines 57-67].

Yamashita et al are silent to coordinate transformation section for transforming positions on the head surface to brain surface coordinates.

Yamashita teach in fig 3-5 the incident, detection positions as taught (are used as virtual markers). Applicant discloses in [0047-0048] that projection points on brain surface are determined with the international 10-20 system on head surface (for standard points).

However, Lagerlund et al teach 10-20 system using 3D MRI scanning with markers [see abstract and title] and determining positions of electrodes to provide coordinates that can be used for analysis of EEG recordings [see page 7]; determining locations of 33 scalp electrodes used for electroencephalography (EEG) recording by placing markers in tile positions determined by the 10-20 system and performing magnetic resonance image (MRI) scanning on volunteer subjects. Small Vaseline-filled

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capsules glued on the scalp with collodion produced easily delineated regions of increased signal on standard MRI bead images. Measurements of each capsule's coordinates in 3 dimensions were made from MRI scans [see abstract].

However, Towle et al teach the international 10-20 system electrode positions and 14 fiducial landmarks are described in cartesian coordinates (± 1.4 mm average accuracy). Test-retest reliability depended on the electrode position with greater measurement errors (maximum 7 mm) than midline locations. Location variability due to head shape was greatest in the temporal region, averaging 5 mm from the mean. For each subject's electrode locations a best-fitting sphere was determined (79-87 mm radius, 6% average error). A surface-fitting algorithm was used to transfer the electrode locations and best-fitting sphere to MR images of the brain and scalp [see summary]. Towle further teach cartesian coordinates were determined using localized device [see page 2, methods].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Yamashita et al. Towle et al and Lagerlund references by implementing a coordinate transforming section into the processor as taught by Yamashita et al; for the purpose diagnosing the brain with great accuracy and higher precision.

Regarding claims 2, 4-7, 12-13, and 15, all other limitations are taught as set forth by the above combination.

Yamashita et al are silent to normalizing brain surface coordinates onto a standard brain; calculating coordinates of arbitrary points.

However, Lagerlund et al disclose the international 10-20 system as described above, can be used to normalize head images of subjects into a standard brain.

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Yamashita et al and Lagerlund references by using the 10-20 system to calculate arbitrary coordinate points and to normalize into a standard brain; to have a general diagnosis of an area of the brain.

Regarding claims 8, all other limitations are taught as set forth by the above combination.

Yamashita et al are silent to probability error information.

However, Towle et al teach test-retest reliability depended on the electrode position with greater measurement errors (maximum 7 mm) than midline locations. Location variability due to head shape was greatest in the temporal region, averaging 5 mm from the mean. For each subject's electrode locations a best-fitting sphere was determined (79-87 mm radius, 6% average error) [see abstract].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Yamashita et al and Towle et al references by calculating a probability error; in order to compensate for erroneous measurements and to increase the reliability of the diagnosis.

Regarding claims 3, 9-10, and 16, all other limitations are taught as set forth by the above combination.

Yamashita et al are silent to distance search method.

However, Towle et al teach a computer program that could be used to realize the method [see page 2, methods]; finding the radial distance [see page 2, methods].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Yamashita et al and Towle et al by using a distance method as taught by Towle et al; for accuracy and precision.

Regarding claim 14, all other limitations are taught a set forth by the above combination.

The above combination is silent to the near infrared.

However, Yamashita et al teach semiconductor lasers each emitting the light of multiple wavelengths from visible to infrared ray ranges, for example, 2 wavelengths of 780 nm and 830 nm. Values of these two wavelengths are not restricted to 780 nm and 830 nm. Further, the number of wavelengths is not limited to two. A light emitting diode may be used as this light source instead of a semiconductor laser [see column 5 lines 60-67 and column 6 lines 1-35]. Yamashita et al further teach the usefulness of image measurement of the living body using said light is also described, for example, in Atsushi Maki, et al. "Spatial and temporal analysis of human motor activity using

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noninvasive NIR topography", 1995, Medical Physics, Vol. 22, P.P. 1997 to 2005) [see column 2 lines 13-32].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to modify the Yamashita et al reference by using near infrared region; because the living body is not harmed by application of the light.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768